REMARKS

This Amendment is in response to the Office Action, dated November 29, 2006 ("Office Action"). It is respectfully submitted that the application is in condition for allowance. Claims 1, 3-8, 10-18, 20 and 22-28 were pending; claims 4-8, 10-18, 20, 22 and 28 were withdrawn from consideration; and claims 1, 3 and 23-27 were rejected. Claims 4, 7-8, 12-14, 23-24 and 27-28 have been amended; claims 1, 3, 5-6, 25-26 have been canceled (claims 2, 9, 19 and 21 having previously been canceled); and new claims 29-30 have been added by virtue of the present amendment. No new matter has been added. Allowance and reconsideration of the application in view of Applicants' amendment and the ensuing remarks is respectfully requested.

On February 14, 2007, an Interview was conducted with Examiners Deborah K. Ware and David Naff. Applicants thank Examiners Ware and Naff for their time and guidance. During the Interview, U.S. Pat. No. 5,516,533 (Badylak *et al.*) and Pat. Application Publication No. 2002/0183857 (Yang) were discussed. U.S. Pat. No. 6,497,872 (Weiss *et al.*) and U.S. Pat. No. 4,663,295 (Vail *et al.*) were also briefly discussed. Examiners were of the opinion that a portion of an organ may be interpreted as a blood vessel. Applicants respectfully disagree with this interpretation and submit that the interpretation by Examiners is taken out of context of the claim and the specification. Examiners indicated that a product by process claim that includes a sonication step may be allowable as the resulting tissue powder may be different over the prior art.

Claim 4 was amended to include the limitations of claim 23. Thus, claim 4 recites that the tissue powder is a *fine* tissue powder and that the tissue powder is produced by "providing the full and intact whole organ or the full and intact whole tissue; grinding the full and intact whole organ or the full and intact whole tissue to produce a ground tissue powder and sonicating the ground tissue powder to produce the fine tissue powder." Support for this amendment may be found throughout the specification.

Claims 7 and 8 have been amended to adjust claim dependency and to improve clarity.

Claims 12 and 13 have been amended to correct a minor grammatical error.

Claim 14 has been amended to include the limitations of claim 23. Thus, claim 4 recites that the tissue powder is a *fine* tissue powder and that the tissue powder is produced by "providing the full and intact whole organ or the full and intact whole tissue; grinding the full and intact whole organ or the full and intact whole tissue to produce a ground tissue powder and sonicating the ground tissue powder to produce the fine tissue powder." Support for this amendment may be found throughout the specification.

Claim 23 has been amended to delete "a portion of a full and intact whole organ," and "a portion of a full and intact whole tissue" from the claim. The claim was also amended to improve clarity.

Claim 24 has been amended to recite that the tissue powder is a *fine* tissue powder. The claim was further amended to recite the process of producing the cell culture matrix composition. Support for this amendment may be found throughout the Specification.

Claim 27 has been amended to recite the step of "providing the full and intact whole organ." Support for this amendment may be found throughout the specification.

Claim 28 has been amended to recite that the tissue powder is a *fine* tissue powder. The claim was further amended to recite the process of producing the fine tissue powder.

In the Office Action, Examiner deemed that the Restriction Requirement issued on February 22, 2006, was proper and thus made final. Examiner withdrew from consideration Claims 4-8, 10-18, 20, 22 and 28.

Examiner rejected claims 1 and 3 under 35 U.S.C. §102(b) as being anticipated by Badylak *et al.* (U.S. Patent No. 5,516,533). Examiner found that Badylak *et al.* "*teach a cell culture matrix composition comprising a tissue powder derived from an intestinal segment and the composition may further comprise a medium,*" and found that the claims are identical to the disclosure of Badylak *et al.* Examiner found that the claims of the present application require a portion of whole tissue, which reads on an intestinal segment tissue as disclosed by Badylak *et al.* Further, Examiner noted that while Badylak *et al.* did not use the entire segment of the intestine, "*the prior art has*

been applied on the basis of tissue powder and not layers, per se." Examiner noted that Badylak *et al.* did not use the entire segment of the intestine. However, Examiner stated that the term "comprising" does not omit tissue powder derived from the intestinal segment described by Badylak *et al.* Further, Examiner, citing the abstract, found that Badylak *et al.* taught that the cell culture matrix may be derived from the intestinal submucosa comprising a segment of the intestinal tissue. Although Applicants in no way concede to the merit of this rejection, claims 1 and 3 have been canceled and thus, this rejection is rendered moot.

Examiner rejected claims 1, 3, and 23-27 under 35 U.S.C. §102(a) as being anticipated by Yang. Examiner found that Yang taught cell culture matrix compositions comprising tissue powder comprising a segment of a blood vessel and a method for producing the tissue powder. Examiner found that the claims of the present application require a portion of whole tissue, which reads on an intestinal segment tissue as disclosed by Badylak *et al.* Applicants presume that Examiner intended to assert that the claims read on the blood vessels as disclosed by Yang. Further, Examiner noted that "*the prior art has been applied on the basis of tissue powder and not layers, per se.*" As to canceled claims 1, 3, and 25-26, this rejection is rendered moot. As to claims 23-24 and 27, Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference (MPEP §2131 (citing Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987)).

Claim 23 as amended describes a fine tissue powder derived from a full and intact whole organ or a full and intact whole tissue and produced by a method that includes a sonication step. Yang does not describe the use of a sonication step, which converts the ground tissue powder to a fine tissue powder to produce the cell culture matrix composition. Claim 23 as amended is thus not anticipated by the tissue powder derived from the blood vessel disclosed by Yang.

Similarly, claim 24 as amended describes a fine tissue powder derived from a full and intact whole liver and produced by a method that includes a sonication step. Yang

does not describe the use of a sonication step, which converts the ground tissue powder to a fine tissue powder to produce the cell culture matrix composition. Claim 24 as amended is thus not anticipated by the tissue powder derived from the blood vessel, as disclosed by Yang.

Likewise, claim 27 as amended describes a fine tissue powder derived from a full and intact whole organ and produced by a method that includes a sonication step. Yang does not describe the use of a sonication step, which converts the ground tissue powder to a fine tissue powder to produce the cell culture matrix composition. Claim 27 as amended is thus not anticipated by the tissue powder derived from the blood vessel disclosed by Yang.

The cell matrix compositions of claims 23, 24, 27 and claims that depend therefrom are different than that disclosed by Yang in that they are derived from the full and intact organ or tissue, which includes "many or all of the essential elements which cells contact and interact with *in vivo* within specific organs" which "provides a more comprehensive biological support for cell culture." See, *e.g.*, specification, page 5, lines 27-30. The tissue powder derived from Yang is of a different composition than the tissue powder of the present claims because Yang's tissue powder is derived from several layers of the blood vessels and specifically removes the endothelial layer and part of the aventitia layer from being part of the composition (see Yang, page 4, para. 33). Thus, without being derived from the full and intact blood vessel, Yang's tissue powder differs from the tissue powder of claims 23, 24, and 27 (and claims that depend therefrom) because they are derived from the full and intact whole organ or full and intact whole tissue.

In light of the foregoing remarks, Applicants respectfully submit that Yang does not anticipate claims 23-27, and therefore request reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(b).

Examiner rejected claims 1, 3 and 23-27 under 35 U.S.C. §103(a) as being unpatentable over Badylak *et al.*, in light of Weiss *et al.* and Vail *et al.* Examiner found that the intestinal tissue disclosed by Badylak *et al.* "is not less than a portion." Examiner found that sonication is disclosed in the prior art and one of skill in the art

would have been motivated to use sonication to produce the powder form of the organ because it has been disclosed to be useful for preparation of products similar to the claimed tissue powder. Examiner found that "since the process steps are not required for the patentability of the claimed product[,] the prior art need not teach these process steps." Examiner did not comment on Weiss *et al.* However, based on previous office actions, Applicants presume that Examiner cited Weiss *et al.* to assert that perfusion techniques have been taught in the prior art which, according to the Examiner, renders the claims prima facie obvious. As to canceled claims 1, 3, and 25-26, this rejection is rendered moot. As to claims 23-24 and 27, Applicants respectfully traverse this rejection.

Three basic criteria must be met to establish a prima facie case of obviousness: (1) "*there must be some suggestion or motivation . . . to combine reference teachings*," (2) "*there must be a reasonable expectation of success*," and (3) the prior art references "*must teach or suggest all the claim limitations*." MPEP § 2142 (emphasis added).

Claim 23 as amended describes a fine tissue powder derived from a full and intact whole organ or a full and intact whole tissue and produced by a method that includes a sonication step. Badylak *et al.* does not describe the use of a sonication step, which converts the ground tissue powder to a fine tissue powder to produce the cell culture matrix composition. Claim 23 as amended is thus not anticipated by the tissue powder derived from the intestinal submucosa, as disclosed by Badylak *et al.*

Claim 24 recites the use of a liver to derive the tissue powder and not intestinal submucosa. Thus, Badylak *et al.*, which recites the use of intestinal submucosa to produce a cell matrix composition, does not anticipate claim 24. Further, even assuming that Examiner may have intended to reject claim 24 based on Yang, claim 24 as amended describes a fine tissue powder derived from a full and intact whole liver and produced by a method that includes a sonication step. Yang does not describe the use of a sonication step, which converts the ground tissue powder to a fine tissue powder, to produce the cell culture matrix composition. Claim 24 as amended is thus not anticipated by the tissue powder derived from the blood vessel, as disclosed by Yang.

Likewise, claim 27 as amended describes a fine tissue powder derived from a full and intact whole organ and produced by a method that includes a sonication step. Badylak *et al.* does not describe the use of a sonication step, which converts the ground tissue powder to a fine tissue powder, to produce the cell culture matrix composition. Claim 27 as amended is thus not anticipated by the tissue powder derived from the intestinal submucosa, as disclosed by Badylak *et al.*

Moreover, the cell matrix compositions of claims 23, 24, and 27 and claims that depend therefrom are different than that disclosed by Badylak *et al.* or Yang in that they are derived from the full and intact organ or tissue, which includes "many or all of the essential elements which cells contact and interact with *in vivo* within specific organs" which "provides a more comprehensive biological support for cell culture." See, *e.g.*, specification, page 5, lines 27-30. The tissue powder derived from Badylak *et al.* is of a different composition than the tissue powder of the present claims because Badylak's tissue powder is derived from several layers of the intestinal submucosa ("delaminated from the tunica muscularis and the luminal portion of the tunica mucosa of said segment" (Col. 2, lines 30-35)). Thus, without the full and intact intestinal segment, Badylak's tissue powder differs from the tissue powder of claims 23, 24 and 27 (and claims that depend therefrom) because they are derived from the full and intact whole organ or full and intact whole tissue.

Further, Applicants respectfully submit that Examiner's combination of references is improper. Weiss *et al.* relates to transplanting stem cells. The perfusion technique discussed in Weiss *et al.* related to perfusion of the left ventricle prior to studying the spinal cords. (See column 43.) There was no suggestion or motivation in Badylak *et al.* or Weiss *et al.* that leads one of skill in the art to use perfusion techniques to isolate the organ or tissue to produce a cell culture matrix composition. Vail *et al.* used sonication to homogenize the material. There was no suggestion or motivation in Vail *et al.* or Badylak *et al.* that leads one of skill in the art to use sonication techniques to produce the fine tissue powder. However, while Applicants in no way concede that Examiner's combination of references is proper herein, even if the combination is proper, the cited combination of references -- supplementing the aforementioned references with

information regarding perfusion and sonication techniques -- still does not teach or suggest all of the limitations of Applicants' claims.

In light of the foregoing remarks, Applicants respectfully submit that the combination of Badylak *et al.*, Weiss *et al.* and Vail *et al.* does not anticipate claims 22-25 and 27 and therefore request reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a).

Applicants respectfully draw Examiner's attention to the following:

> "Where claims directed to a product and to a process of making and/or using the product are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or a process . . . However, if applicant elects claim(s) directed to the product, which is subsequently found allowable, withdrawn process claims which...require all the limitations of an allowable product claim will be considered for rejoinder." MPEP § 821.04(b).

Applicants respectfully submit that independent product claims 23, 24 and 27 as amended, are allowable. Claims 4, 7-8, 10-18, 20, 22 and 28 contain all the limitations of claim 23. Thus, claims 4, 7-8, 10-18, 20, 22 and 28, directed to process of making or using the allowable product, should be considered for rejoinder and should be rejoined because the process claims commensurate in scope with an allowable product claim. In light of the foregoing, Applicants respectfully request consideration for the rejoinder and rejoinder of claims 4, 7-8, 10-18, 20, 22 and 28.

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All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. If for any reason Examiner finds the application other than in condition for allowance, Examiner is requested to call either of the undersigned attorneys at the Los Angeles telephone number (213) 633-6800 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,
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Attachment: Petition for a Two-Month Extension of Time

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